UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,499	10/11/2000	Roy Curtiss III	3116-1192	5788

7590 01/29/2002

Elie H Gendloff
Howell & Haferkamp LC
7733 Forsyth Blvd
Suite 1400
St Louis, MO 63105

EXAMINER
SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/686,499	CURTISS, ROY	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *10* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment B and response received 10/15/ 2001, paper 8 is acknowledged. Claims 1, 3, 7 and 12-16 were amended.

2. Applicant's amendment C received 11/08/ 2001, paper 9 is acknowledged. Claim 3 was amended for the second time (see interview summary report paper # 10).

3. Currently claims 1-22 are pending and under consideration.

Prior Citations of Title 35 Sections

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Rejections Withdrawn

5. Rejection of claims 1, 3, 6, 11-12 and 14 under 35 U.S.C. 112 second paragraph made in paragraph 6 of the office action mailed on April 06, 2001 (paper number 4) is withdrawn in view of applicant's amendments of those claims.

6. Rejection of claims 1-22 under 35 U.S.C. 103 (a) made in paragraph 7 of the office action mailed on April 06, 2001 (paper number 4) is withdrawn in view of applicant's arguments and amendments.

New grounds for rejections

Claim Rejections - 35 USC § 102(b)

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Nayak et al., (Infection and immunity Vol. 66 No. 8 pp. 3744 –3751, 1998) Prior art already made of record.

Claims are drawn to an attenuated derivative of a pathogenic microorganism (Enterobacteriaceae) comprising a non functional native essential gene (asd) and a recombinant complementing gene on a vector (plasmid) encoding a replacement for an essential enzyme.

Nayak et al. teach an attenuated *Salmonella typhimurium* with cya and crp gene mutations (non functional essential native chromosomal gene). Stable expression of a bacterial antigen (*Streptococcus pneumoniae* surface protein A) was achieved by the use of the balanced-lethal host-vector system (see abstract), which employs an asd deletion in the host chromosome to impose an obligate requirement for diaminopimelic acid (DAP) (see abstract). They also used Asd+ vector pYA3148 or the recombinant plasmid pYA 3193 (page 3747). The prior art discloses the claimed products.

Since the office does not have the facilities for examining and comparing applicant's products with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i. e., that the products of prior art does not possess the same material structure and functional characteristics of the claimed products). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. Claims 1-7 and 12-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Curtiss III et al., (US Patents Number 6024961) Prior art already made of record.

Claims are drawn to an attenuated derivative of a pathogenic microorganism (Enterobacteriaceae) comprising a non functional native essential gene and a recombinant complementing gene on a vector (plasmid) encoding a replacement for an essential enzyme.

And the desired gene product is a bacterial antigen. The above product was achieved by the use of the balanced- lethal host-vector system.

Curtiss III et al. (US Patent No. 6024961) disclose an avirulent immunogenic strain of *Salmonella enterica* serotype Typhi having a mutation in one or more genes comprising of pab, pur, aro, asd, dap, nadA, pncB, galE, pmi, fur, rpsL, ompR, htrA, hemA, cdt, cya, crp, phoP, phoQ, rfc, poxA, galU, or a combination thereof. (See claims, figures specially figure 7 and abstract) They also teach a recombinant gene encoding the desired gene product (see column 11). They disclose bacterial antigens (column 11). They also disclose recombinant vectors (example 2, column 28) and desired gene product cytokine (columns 10 and 11). The prior art discloses the claimed products.

Since the office does not have the facilities for examining and comparing applicant's products with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i. e., that the products of prior art does not possess the same material structure and functional characteristics of the claimed products). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 102(e)

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined

was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1, 2, 8- 13, 16 and 21-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Portnoy et al. (US Patent 6,004,815).

Claims are drawn to an attenuated derivative of a pathogenic microorganism, recombinant vector and a gene operably linked to an eukaryotic promoter.

Portnoy et al. disclose an attenuated derivative of a pathogenic microorganism (*E.coli*) (see abstract, table 1 and claims 1-6), plasmid vectors (column 8, table 2) and gene operably linked to an eukaryotic promoter (CMV) (see column 3). They teach *E. coli* deficient in the production of DAP (see column 16) and a recombinant complementing gene on a vector (plasmid pWR 100 from *Shigella flexneri* (column 16). The prior art discloses the claimed products.

Since the office does not have the facilities for examining and comparing applicant's products with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i. e., that the products of prior art does not possess the same material structure and functional characteristics of the claimed products). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

10. Claims 1-22 stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The

examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

11/22/02

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

MARK NAVARRO
PRIMARY EXAMINER